

10370 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

6505-527-6885 (P. D. No. 4)

- (c) the phrase "100 tablets" or a similar phrase
- (d) the stock number
- (e) the lot or control number
- (f) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear. When both names are placed on the label, the following designations shall precede the names:
"MFR" for the manufacturer and
"CONTR" for the contractor.
- (g) the expiration date
- (h) the statement "Caution: Federal law prohibits dispensing without prescription."
- (i) the following or similar statement: "Keep container tightly closed and store in a dry place, protected from sunlight and excessive heat."
- (j) the recommended dosage

Unit packages. Each unit package label shall bear the same information as required for the label of the immediate container.

Circulars. A circular, brochure, or other printed matter shall be packaged within each unit package setting forth as a minimum: Indications for use, Administration, Precautions, Toxicity, and Side Effects.

Packaging.

Unit of issue. One bottle containing 100 tablets, as specified, constitutes one unit of issue.

Unit package. Each unit shall be packaged as specified in 5.2.5.

Intermediate package. The number of units of issue specified for Procedure Code 4 shall be intermediate packaged in accordance with 5.3, except partitions shall not be required when unit package is furnished.